



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

December 20, 2005

**FILE COPY**

Steve Richardson  
Director, Regulatory Affairs  
Mayne Pharma (USA) Inc.  
650 From Road, Second Floor  
Paramus, NJ 07652

Dear Mr. Richardson:

Your petition requesting the Food and Drug Administration to make a determination that an Abbreviated New Drug Application may be submitted for Irinotecan Hydrochloride Injection was received by this office on 12/20/2005. It was assigned docket number 2005P-0496/CP 1 and it was filed on 12/20/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0496

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